

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Substitute  
Declaration for Patent Application

As a named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated next to my name;

I believe I am the original, first and sole inventor (if only one name is listed) or an original, first and joint inventor (if plural names are listed in the signatory page(s) commencing at page 3 hereof) of the subject matter which is claimed and for which a patent is sought on the invention entitled

IN VIVO PRODUCTION AND DELIVERY OF ERYTHROPOIETIN OR

INSULINOTROPIN FOR GENE THERAPY

the specification of which (check one)

☐ is attached hereto.

☒ was filed on July 10, 1992 as  
Application Serial No 07/911,533  
and was amended on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known by me to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

			Priority Claimed	
(Number)	(Country)	(Day/Month/Year filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>

[illegible]

07/787,840	November 5, 1991	Abandoned
(Application Serial No.)	(Filing date)	(Status, patented, pending, abandoned)
07/789,188	November 5, 1991	Abandoned
(Application Serial No.)	(Filing date)	(Status, patented, pending, abandoned)

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

I also hereby grant additional Powers of Attorney to the following attorney(s) and/or agent(s) to file and prosecute an international application under the Patent Cooperation Treaty based upon the above-identified application, including a power to meet all designated office requirements for designated states.

David E. Brook	Registration No. 22,592
James M. Smith	Registration No. 28,043
Leo R. Reynolds	Registration No. 20,884
Richard A. Wise	Registration No. 18,041
Patricia Granahan	Registration No. 32,227
Mary Lou Wakimura	Registration No. 31,804
Thomas O. Hoover	Registration No. 32,470
Alice O. Carroll	Registration No. 33,542

all of Hamilton, Brook, Smith and Reynolds, P.C., Two Militia Drive, Lexington, Massachusetts 02173;

and

Send correspondence to: Patricia Granahan

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

Two Militia Drive, Lexington, Massachusetts 02173

Direct telephone calls to: Patricia Granahan

(617) 861-6240

Full name of fourth joint  
inventor, if any \_\_\_\_\_  
Fourth Inventor's  
Signature \_\_\_\_\_ Date \_\_\_\_\_  
Residence \_\_\_\_\_  
\_\_\_\_\_  
Citizenship \_\_\_\_\_  
Post Office Address \_\_\_\_\_

[illegible]

Richard F Selden, Douglas Treco  
Applicant or Patentee: and Michael W. Heartlein Attorney's  
Serial or Patent No.: 07/911,533 Docket No.: TKT91-01A  
Filed or Issued: July 10, 1992  
For: IN VIVO PRODUCTION AND DELIVERY OF ERYTHROPOIETIN OR  
INSULINOTROPIN FOR GENE THERAPY

COPY

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) and 1.27(c) - SMALL BUSINESS CONCERN

I hereby declare that I am

[ ] the owner of the small business concern identified below:

[X] an official of the small business concern empowered to act on behalf  
of the concern identified below:

NAME OF CONCERN Transkaryotic Therapies, Inc.

ADDRESS OF CONCERN 195 Albany Street

Cambridge, MA 02115

I hereby declare that the above identified small business concern qualifies  
as a small business concern as defined in 13 CFR 121.12, and reproduced in  
37 CFR 1.9(d), for purposes of paying reduced fees to the United States  
Patent and Trademark Office, in that the number of employees of the  
concern, including those of its affiliates, does not exceed 500 persons.  
For purposes of this statement, (1) the number of employees of the business  
concern is the average over the previous fiscal year of the concern of the  
persons employed on a full-time, part-time or temporary basis during each  
of the pay periods of the fiscal year, and (2) concerns are affiliates of  
each other when either, directly or indirectly, one concern controls or has  
the power to control the other, or a third party or parties controls or has  
the power to control both.

I hereby declare that rights under contract or law have been conveyed to  
and remain with the small business concern identified above with regard to  
the invention, entitled IN VIVO PRODUCTION AND DELIVERY OF ERYTHROPOIETIN OR  
INSULINOTROPIN FOR GENE THERAPY

by inventor(s) Richard F selden, Douglas Treco and

Michael W. Heartlein

described in

[ ] the specification filed herewith

[X] application serial no. 07/911,533, filed July 10, 1992.

[ ] patent no. \_\_\_\_\_, issued \_\_\_\_\_.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e). \*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Richard F Selden, M.D., Ph.D.  
TITLE OF PERSON OTHER THAN OWNER Chairman, Board of Scientific Advisors  
ADDRESS OF PERSON SIGNING 195 Albany Street  
Cambridge, MA 02115  
SIGNATURE *Richard F Selden* DATE 08/27/92

COPY

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Declaration for Patent Application

As a named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated next to my name;

I believe I am the original, first and sole inventor (if only one name is listed) or an original, first and joint inventor (if plural names are listed in the signatory page(s) commencing at page 3 hereof) of the subject matter which is claimed and for which a patent is sought on the invention entitled

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☐ was filed on \_\_\_\_\_ as  
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and was amended on \_\_\_\_\_ (if applicable).

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I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority  
Claimed

\_\_\_\_\_  
(Number) (Country) (Day/Month/Year filed) ☐ Yes ☐ No

\_\_\_\_\_  
(Number) (Country) (Day/Month/Year filed) ☐ Yes ☐ No

\_\_\_\_\_  
(Number) (Country) (Day/Month/Year filed) ☐ Yes ☐ No

66333 "06782660

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information known by me to be material to patentability as defined in 37 C.F.R. §1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

07/787,840	November 5, 1991	Pending
(Application Serial No.)	(Filing date)	(Status, patented, pending, abandoned)
<hr/>		
(Application Serial No.)	(Filing date)	(Status, patented, pending, abandoned)

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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Leo R. Reynolds	Registration No. 20,884
Richard A. Wise	Registration No. 18,041
Patricia Granahan	Registration No. 32,227
Mary Lou Wakimura	Registration No. 31,804
Thomas O. Hoover	Registration No. 32,470
Alice O. Carroll	Registration No. 33,542

all of Hamilton, Brook, Smith and Reynolds, P.C., Two Militia Drive, Lexington, Massachusetts 02173;

and

Send correspondence to: Patricia Granahan, Esq.  
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
Two Militia Drive, Lexington, MA 02173

Direct telephone calls to: Patricia Granahan, Esq.

(617) 861-6240

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole  
or first inventor Richard F Selden  
Inventor's  
Signature \_\_\_\_\_ Date \_\_\_\_\_  
Residence 106 Bristol Road  
Wellesley, MA 02181  
Citizenship U.S.A.  
Post Office Address same as above

Full name of second joint  
inventor, if any Douglas Treco  
Second Inventor's  
Signature \_\_\_\_\_ Date \_\_\_\_\_  
Residence 87 Brantwood Road  
Arlington, MA 02174  
Citizenship U.S.A.  
Post Office Address same as above

Full name of third joint  
inventor, if any Michael W. Heartlein  
Third Inventor's  
Signature \_\_\_\_\_ Date \_\_\_\_\_  
Residence 167 Reed Farm Road  
Boxborough, MA 01719  
Citizenship U.S.A.  
Post Office Address same as above

Full name of fourth joint  
inventor, if any \_\_\_\_\_  
Fourth Inventor's  
Signature \_\_\_\_\_ Date \_\_\_\_\_  
Residence \_\_\_\_\_  
Citizenship \_\_\_\_\_  
Post Office Address \_\_\_\_\_



# COPY

PATENT  
ATTORNEY DOCKET NO. 50010/007001

Certificate of Mailing: Date of Deposit: April 17, 1994

I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Matthew G. Doherty  
Printed name of person mailing correspondence

[Signature]  
Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Richard F Selden et al.      Art Unit : 1805  
Serial No. : 08/334,455      Examiner : Schwartzman  
Filed : November 4, 1994  
Title : *IN VIVO* PRODUCTION AND DELIVERY OF ERYTHROPOIETIN  
OR INSULINOTROPIN FOR GENE THERAPY

Assistant Commissioner of Patents and Trademarks  
Washington, DC 20231

### REVOCATION AND NEW POWER OF ATTORNEY

Under 37 CFR §3.73(b) Transkaryotic Therapies, Inc., a corporation, certifies that it is the assignee of 100% of the right, title and interest in the patent application identified above by virtue of:

- ☒ An assignment from the inventors of U.S. Serial No. 07/911,533, of which the patent application identified above is a file wrapper continuation application under 37 CFR §1.62. The assignment was recorded in the Patent and Trademark Office at Reel 6251, Frame 0898 on September 16, 1992.

66333 "CE" 33333

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned, whose title is supplied below, is empowered to act on behalf of the assignee.

The undersigned, acting on behalf of the assignee, hereby revokes all powers of attorney previously granted in the above-identified application and appoints:

Paul T. Clark, Reg. No. 30,162  
Karen Lech Elbing, Reg. No. 35,238  
Clark & Elbing LLP  
176 Federal Street  
Boston, MA 02110-2214

with full power of substitution and revocation, to prosecute the above-identified application and to transact all business in the United States Patent and Trademark Office connected therewith.

All correspondence regarding the application should be sent to Paul T. Clark, Clark & Elbing LLP, 176 Federal Street, Boston, MA 02110-2214, (617) 428-0200.

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[illegible]

Date: 4/11/97

**Richard F Selden, M.D., Ph.D.**  
President and CEO  
Transkaryotic Therapies, Inc.

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